IMDRF International Medical Device Regulators Forum

Session 5:

Saudi FDA
Unique Device Identification (UDI)

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IMDRF International Medical Device Regulators Forum

AGENDA

- ❑ Introduction.
- ❑ SFDA -UDI Requirements & Submission steps.
- ❑ Summary of the experience and the most important considerations for the future

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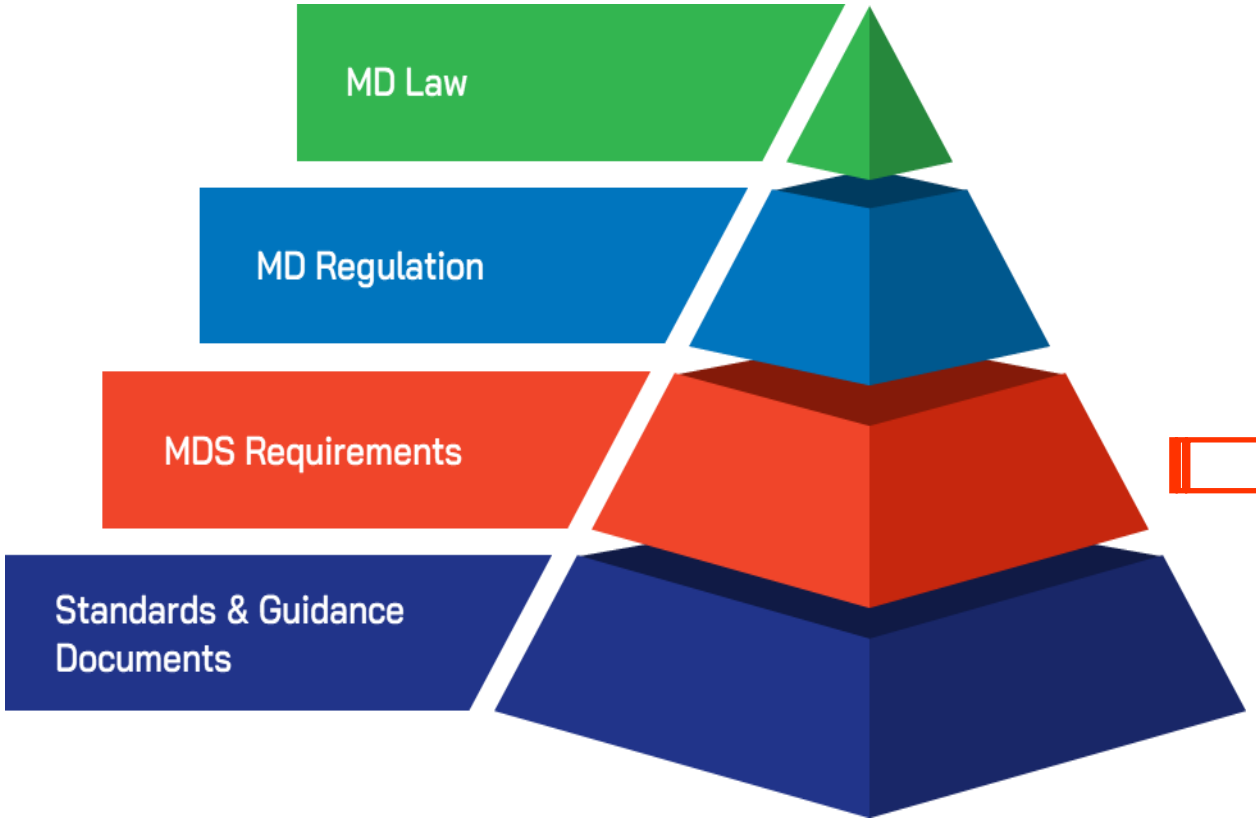
SFDA MD Regulation Framework



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Compliance Dates and The current progress

Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1st October 2020
Risk Class	**Compliance date**
Class B & C (Medium risk) Class D (High risk)	1st September 2023
Class A (Low risk)	1st September 2024

Submitted UDI Records (Aug. 2025)

#of Devices	446703
#of Manufacturers	1797

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Scope

- ✓ **All medical devices & accessories**,
- ✓ The **manufacturer**, or its **authorized representative**, shall submit and maintain the appropriate data in UDI database

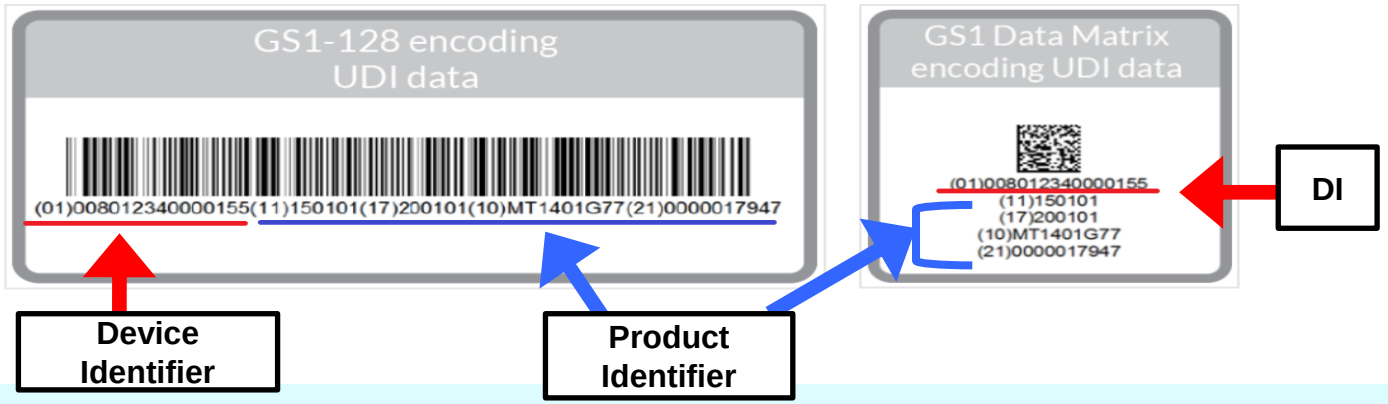
General UDI Requirements include:

- ✓ Recognized issuing Agencies: GS1, HIBCC and ICCBBA
- ✓ The UDI label shall contain two parts: the UDI-DI and the UDI-PI(s).
- ✓ UDI-PI shall include: lot number, serial number, software identification, or expiration (use by) date
- ✓ The UDI shall be readable during normal use and throughout the intended life of the device

UDI in Label

✓ The UDI **must be presented in two forms** on the device label and higher levels of packaging:

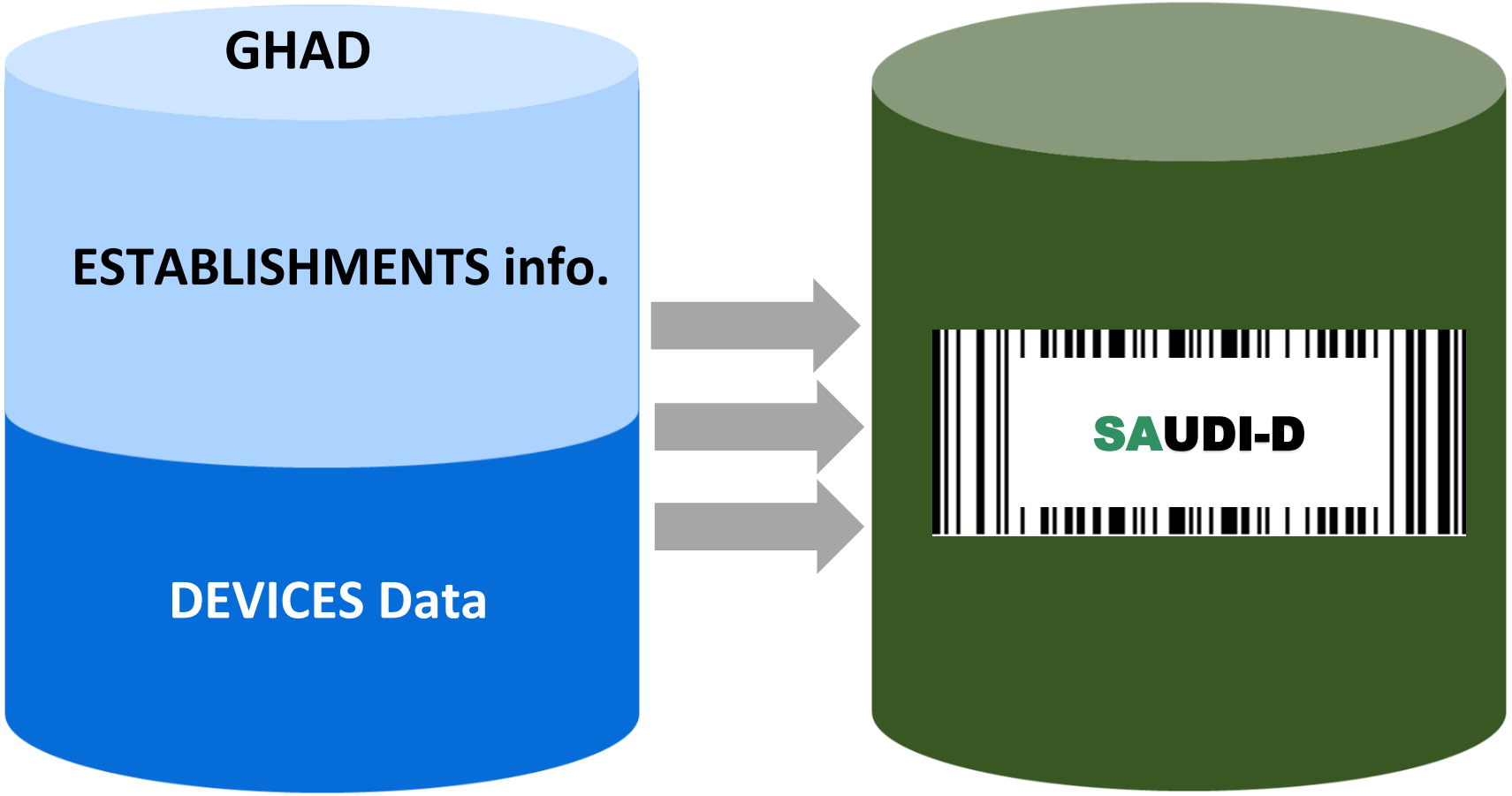
1. **Human Readable Interpretation (HRI):** Easily readable plain-text format.
2. **Automatic Identification and Data Capture (AIDC) Technology**: Such as barcodes (linear or 2D) or RFID, enabling automated scanning and data capture.

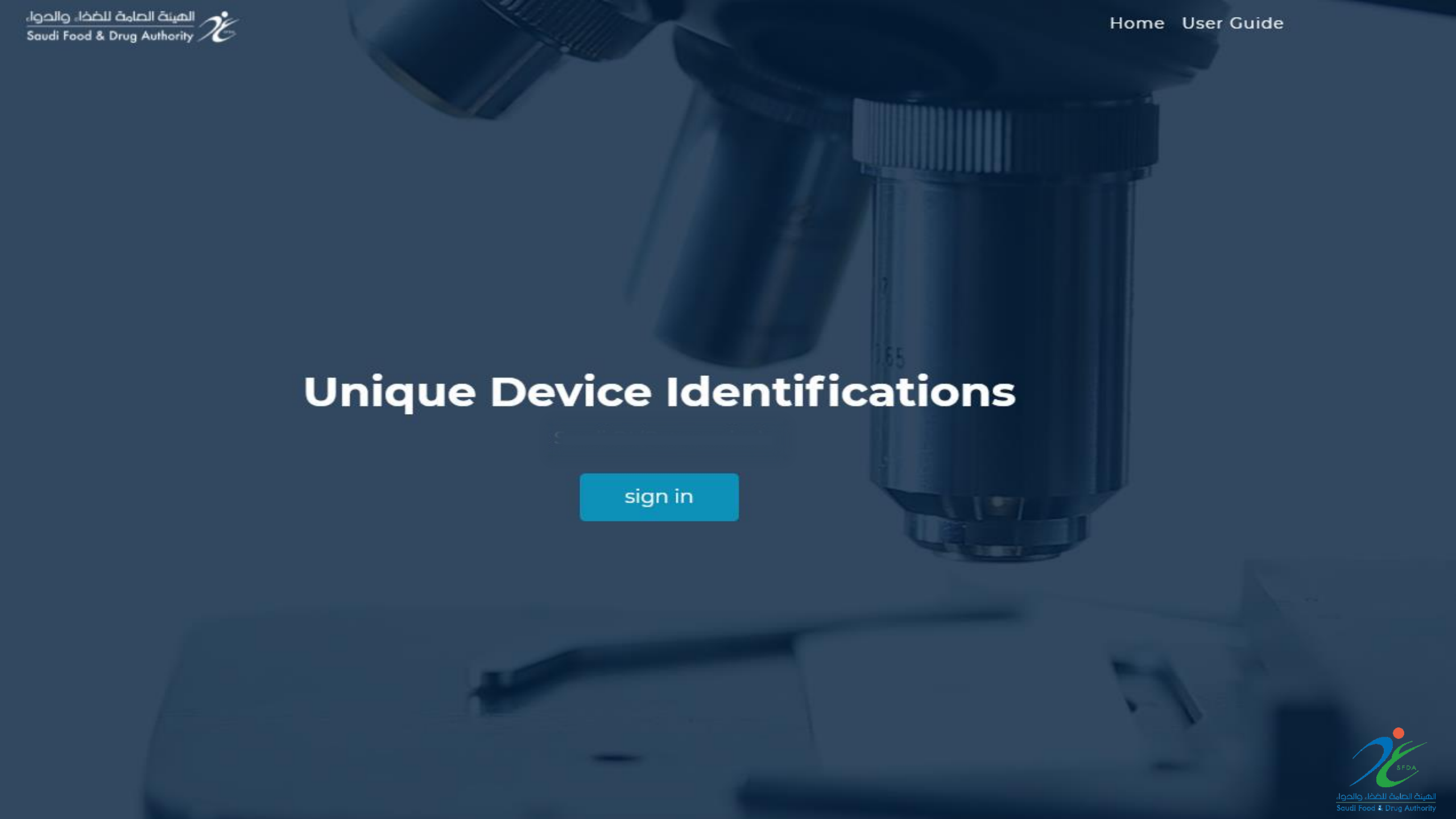


SAUDI-DI Database

- The data shall be available in SAUDI-DI database at the time the device is placed on the market.
- Device Records need to be checked and maintained periodically (at least annually) by the manufacturer or its authorized representative
  - ✓ Revisions shall be made within 10 days when the data changes
  - ✓ ensure the data is accurate and consistent with data submitted to GHAD system modules

SFDA Systems





Unique Device Identifications

sign in

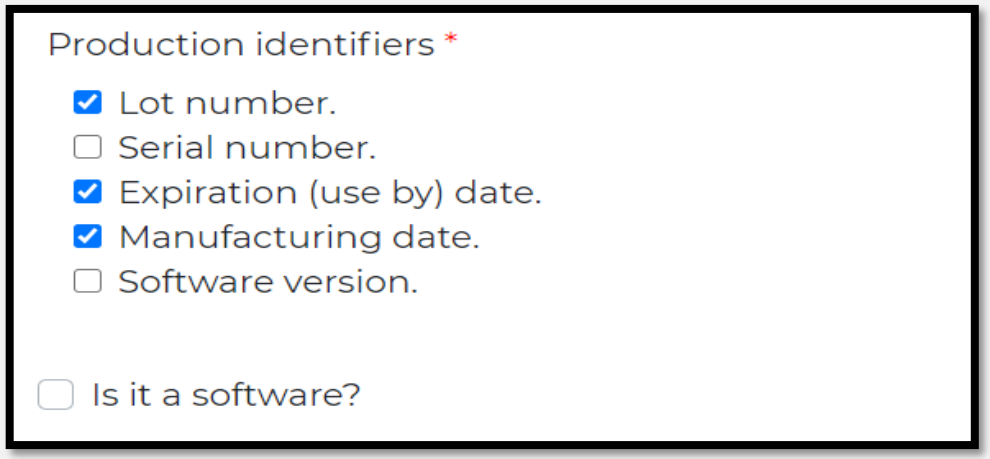
By interring a valid listing number, **all relevant information will be retrieved from Marketing Authorization database.**

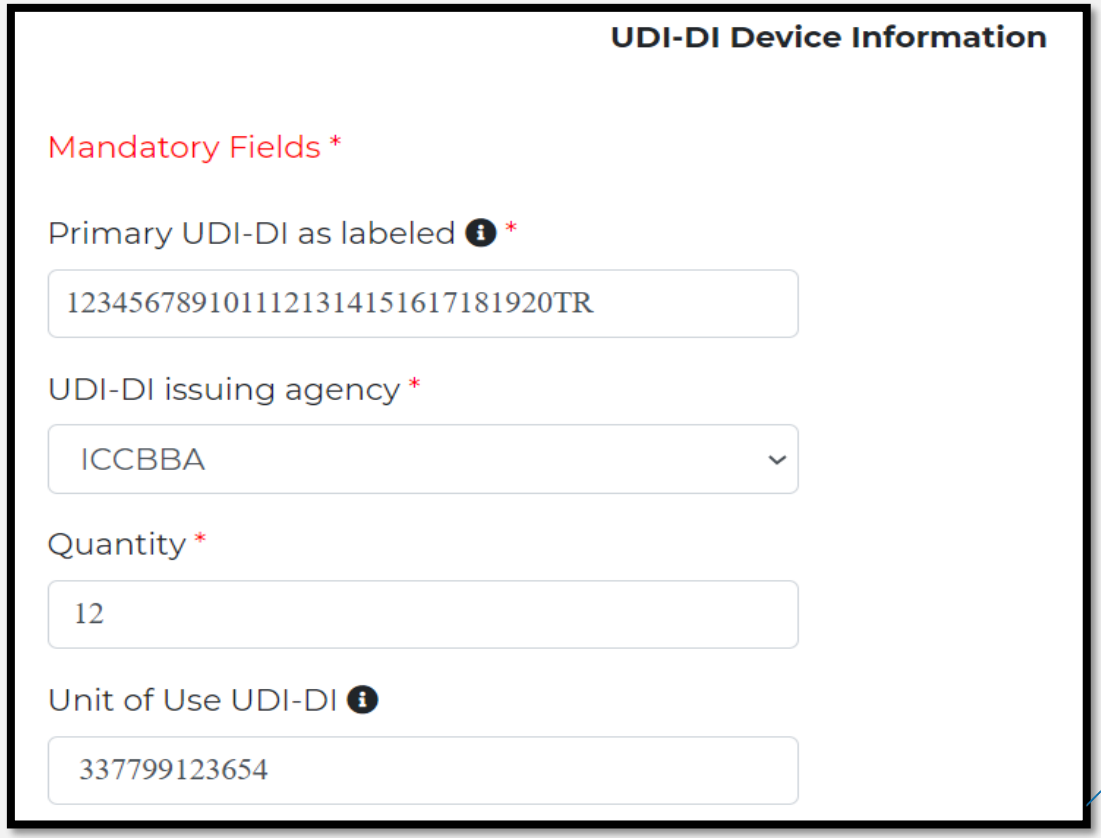
Listing Number	**Authorization Number**
ME00000000091SFDAA00008	MDMA-1-2021-0053
Brand Name	**Device Type**
test Product by Belal	Medical Device
Manufacturer Name	**Device Classification**
Test Manufacturer by Belal	Class III
Manufacturer Number	**Device Description**
ME0000000091	12345678900
Product Name	**sterile Device**
test Product by Belal	-
	Home Use
	No

Primary UDI-DI on the device's primary label, which consider a primary key in the database and to which other DIs are linked to it

UDI-DI issuing agency is selected from drop-down .

Quantity is number of units in this device or package





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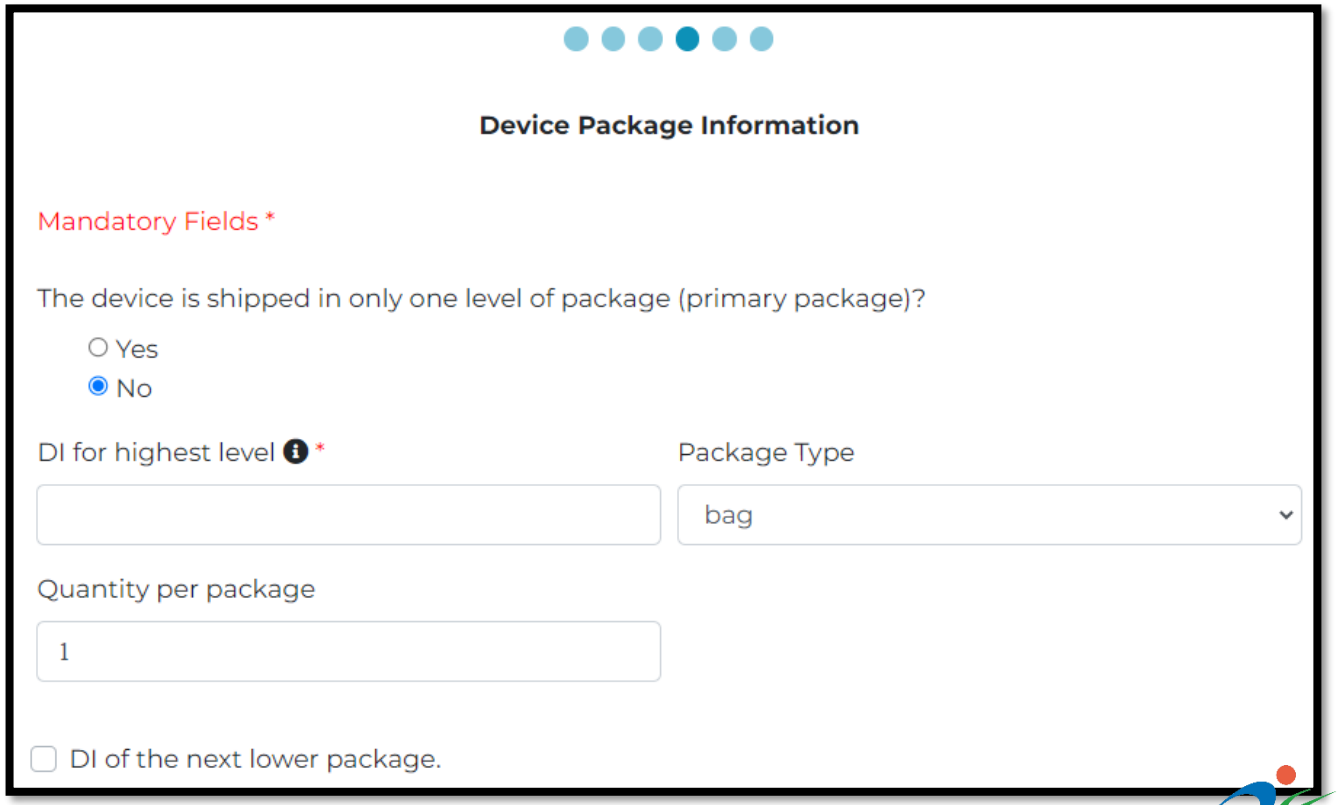
Package UDI-DI

- **Package Information**
- **Add levels of the package hierarchy starting from the bigger level.**

bigger level

Lower level



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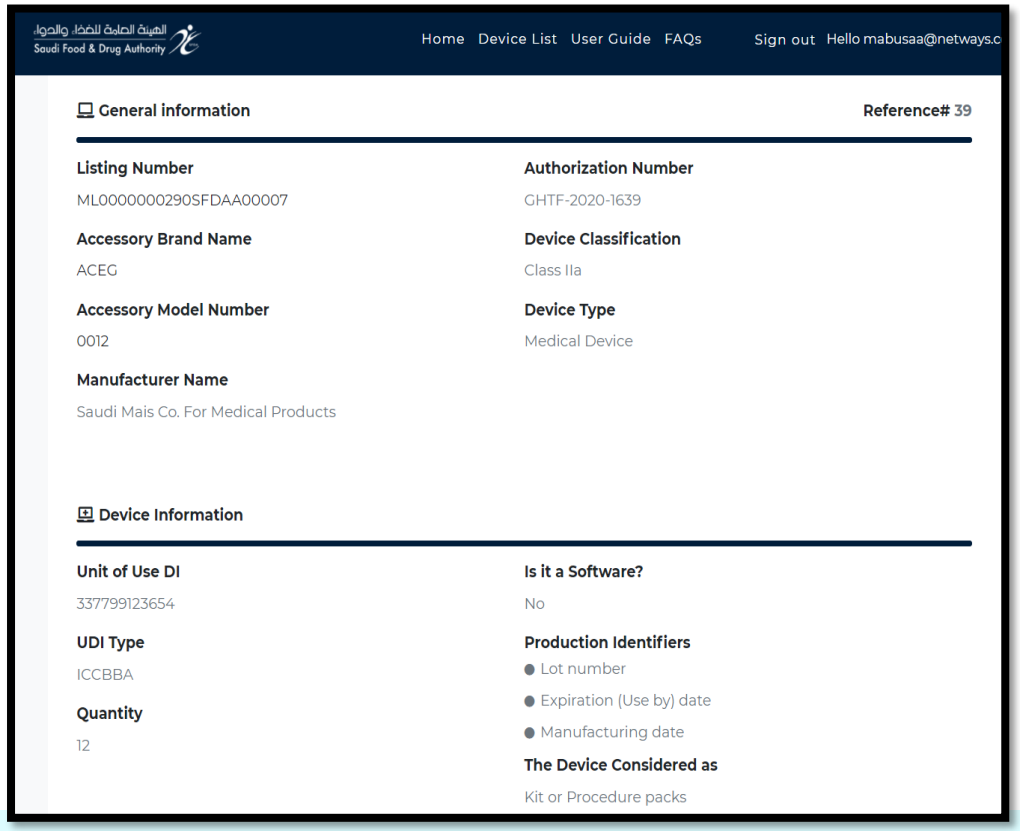
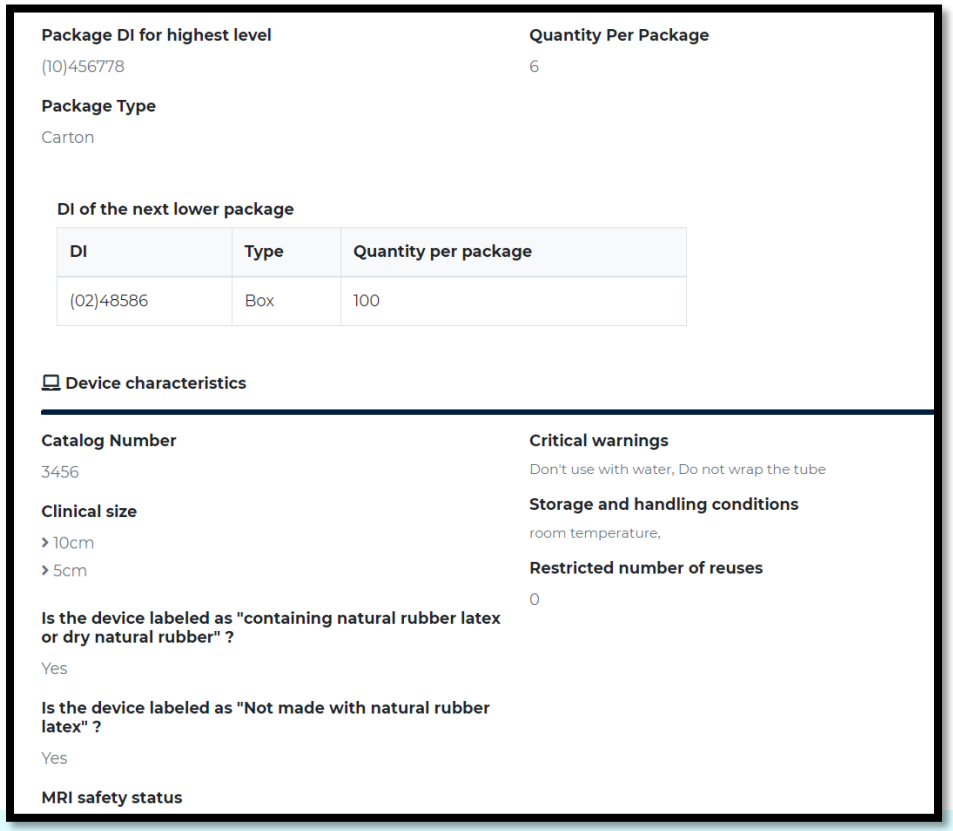
Summary View of Submission

Upon submission, the summary of the record is displayed.





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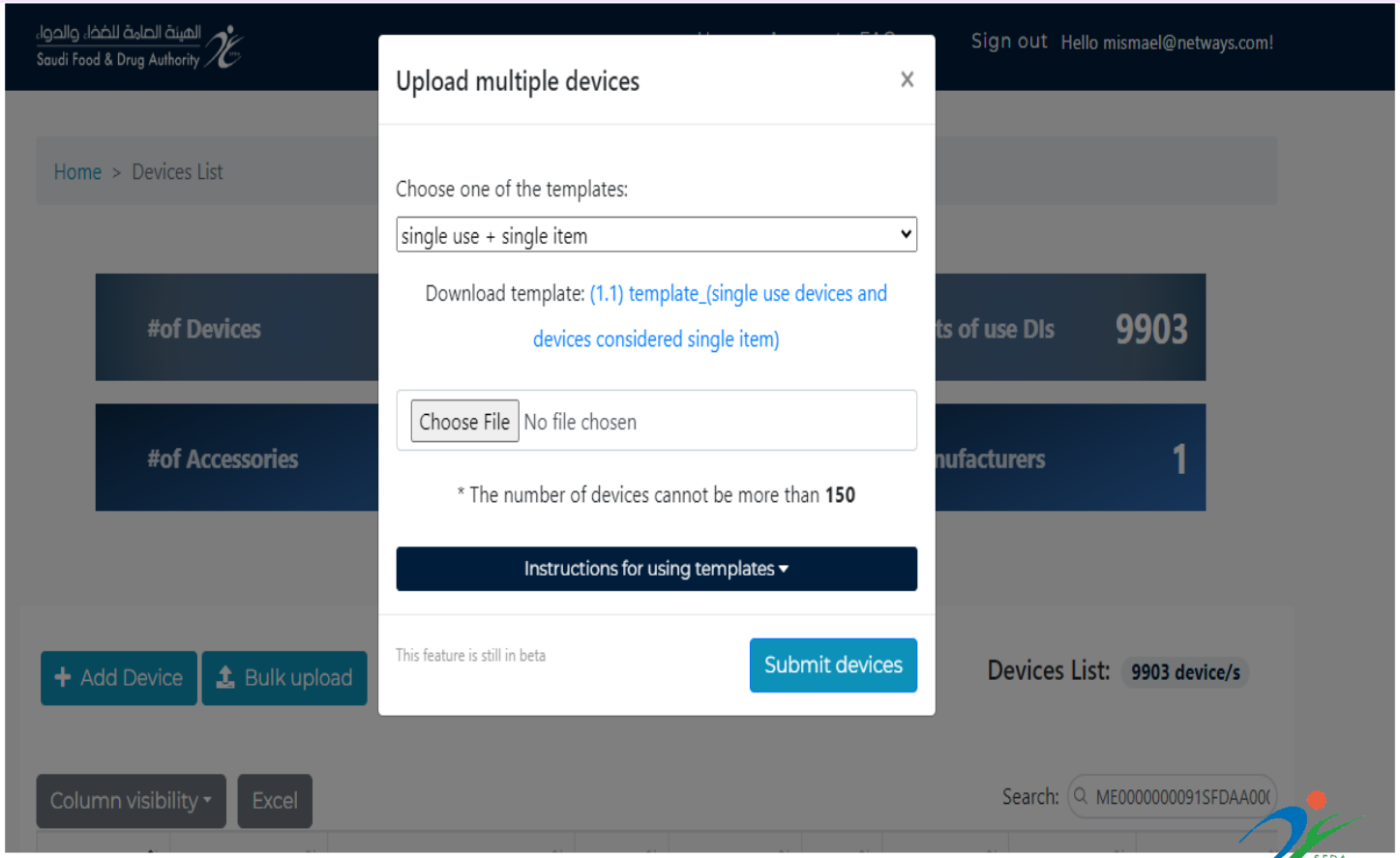
Bulk upload

- Bulk upload for submitting many records in a single Excel sheet
- All data will be automatically saved and displayed within the Devices records list.
- Any wrong data should be corrected individually through the update action.

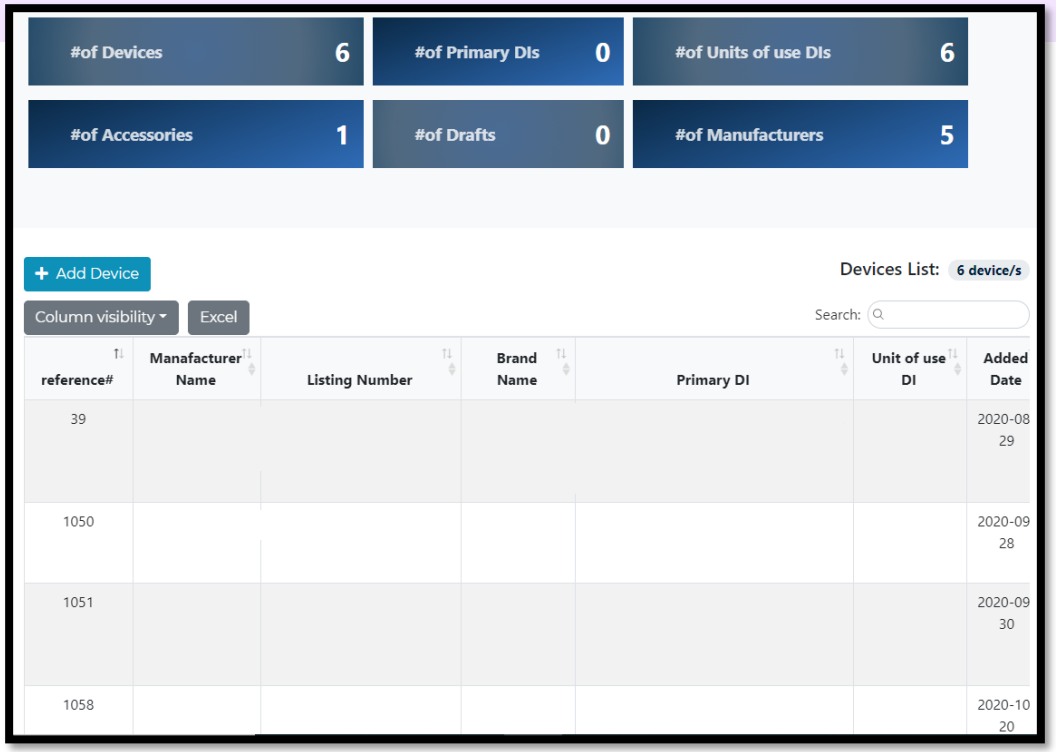


Device List page

Icon Actions

- **Add Device** –to start a new record
- **Column Visibility** – to select the columns displayed
- **Excel** – to export a spreadsheet of records

Search Field



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Summary of the experience and the most important considerations for the future

- The implementation of UDI is a crucial initiative that highlights the **commitment to a safe, transparent, and efficient** medical device ecosystem.
- By establishing clear regulatory requirements ,providing a central database, and implementing a phased compliance approach, the SFDA is actively **enhancing patient safety, improving product traceability**, and bolstering the integrity of the medical device supply chain.
- The Saudi UDI framework is **aligned** with global guidelines and initiatives.
- The **continued collaboration** among manufacturers, healthcare providers, and the SFDA will be crucial in realizing the full potential of UDI, ultimately contributing to a healthier future for the people of Saudi Arabia.

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Summary of the experience and future considerations

- **Ongoing efforts** are crucial to address potential challenges:

  - Awareness and Education
  - Systems Integration
  - Data Quality and Accuracy
  - Technological Adoption
  - Global Harmonization and Continued collaboration.

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Thank You

Contact us at:

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SAUDI-DI

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